

1   **We claim:**

- 1   1.   A crystalline form R of atorvastatin hemi calcium and hydrates thereof.
- 1   2.   Crystalline atorvastatin hemi calcium form R or a hydrate thereof having a powder  
2   XRD pattern substantially as depicted in FIG. 1.
- 1   3.   Crystalline atorvastatin hemi calcium form R or a hydrate thereof having IR  
2   spectrum substantially as depicted in FIG. 2.
- 1   4.   The crystalline form R of atorvastatin hemi calcium of claim 1 exhibiting an XRD  
2   spectrum comprising characteristic peaks at about 8.62, 10.16 and 19.32 degrees  
3   two-theta.
- 1   5.   The crystalline form R of atorvastatin hemi calcium of claim 1 further comprising  
2   peaks at about at 3.6, 8.24, 18.12, 18.36, 20.44, 20.82, 21.22 and 23.82 degrees  
3   two-theta.
- 1   6.   A process for preparing crystalline form R of atorvastatin hemi calcium and  
2   hydrates thereof comprising dissolving crude atorvastatin hemi calcium in a  
3   solvent system comprising tetrahydrofuran and methanol and recovering Form R  
4   atorvastatin hemi calcium or hydrates thereof.
- 1   7.   The process according to claim 6 wherein crude atorvastatin is any of the  
2   polymorphic form reported earlier.
- 1   8.   The process according to claim 6 wherein crude atorvastatin hemi calcium contains  
2   unreacted compounds, side products or other impurities.
- 1   9.   The process according to claim 6 wherein mixture of crude atorvastatin hemi  
2   calcium and solvent system is heated up to reflux.
- 1   10.   The process according to claim 6 wherein Crystalline form R of atorvastatin hemi  
2   calcium and hydrates thereof is precipitated by addition of an anti solvent.
- 1   11.   The process according to claim 10 wherein an anti solvent is water.
- 1   12.   The process according to claim 6 wherein Crystalline form R of atorvastatin hemi  
2   calcium and hydrates thereof is isolated by cooling the reaction mixture to a  
3   temperature of about 20 to 40°C.

- 1 13. The process according to claim 6 and 11 wherein tetrahydrofuran, methanol and
- 2 water are in the volume ratio 1:1:4.
- 1 14. A process for the preparation of stabilized amorphous form of atorvastatin hemi
- 2 calcium comprising dissolving crystalline Form R of atorvastatin hemi calcium and
- 3 hydrates thereof in a solvent, and adding the anti-solvent to the resulting solution.
- 1 15. The process according to claim 14 wherein solvent is selected from the group
- 2 consisting of ketones, esters, chlorinated hydrocarbons, cyclic ethers, alcohols,
- 3 nitriles, dipolar aprotic solvents and mixtures thereof.
- 1 16. The process according to claim 14 wherein anti solvent is selected from the group
- 2 consisting of hydrocarbons and dialkyl ethers.
- 1 17. The process according to claim 14, wherein an antioxidant is added to the
- 2 atorvastatin hemi calcium solution to obtain stabilized amorphous atorvastatin
- 3 hemi calcium.
- 1 18. The process according to claim 17, wherein an antioxidant is selected from the
- 2 group consisting of butylated hydroxyanisole, butylated hydroxytoluene and
- 3 tertiary-butylated hydroquinone.
- 1 19. A pharmaceutical composition comprising crystalline form R of atorvastatin hemi
- 2 calcium or hydrates thereof along with pharmaceutically acceptable excipients,
- 3 diluents and carriers.
- 1 20. A method for treatment or prevention of hyperlipidemia, hypercholesterolemia,
- 2 Alzheimer's disease atherosclerosis, xanthoma and in synergism with other drugs
- 3 for treatment of phytosterolemia lipase deficiency and the like, which comprises
- 4 administering to a patient in need thereof, a therapeutically effective amount of
- 5 Crystalline Form R of atorvastatin hemi calcium or hydrates thereof.
- 1 21. The use of crystalline form R of atorvastatin hemi calcium and hydrates thereof in
- 2 the manufacture of a medicament for the treatment or prevention of
- 3 hyperlipidemia, hypercholesterolemia, Alzheimer's disease, atherosclerosis,
- 4 xanthoma and in synergism with other drugs for treatment of phytosterolemia
- 5 lipase deficiency and the like.

- 1    22. A process for preparing crystalline form R of atorvastatin hemi calcium and
- 2        hydrates thereof comprising dissolving crude atorvastatin hemi calcium in a
- 3        mixture of tetrahydrofuran and methanol, and precipitating with water to obtain
- 4        crystalline form R of atorvastatin hemi calcium.
- 1    23. The process for the preparation of Crystalline Form R of atorvastatin hemi calcium
- 2        or hydrates thereof as herein described and illustrated by the examples herein.